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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,299	11/01/2000	John R. Bianchi	RTI-106	2390

7590 01/05/2004

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EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3732	24

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/704,299	BIANCHI ET AL.	
	Examiner	Art Unit	
	Pedro Philogene	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/05/03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,9,17-19,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (6,210,412) in view of Boyle et al. (6,277,149).

With respect to claim 1, Michelson discloses a biomedical implant (20) for implantation into a spine of a patient comprising an elongated body (22) having a first end (26) for engaging a driving and securing device and a second end (24) for initially engaging adjacent vertebrae, wherein the elongated body comprises a continuously tapered and threaded surface from about 5mm to about 25 mm in length; as set forth in column 7, lines 3-37, lines 59-67, column 8, lines 1-18; wherein the continuously tapered and threaded surface begins at a first position on or proximate to the first end

and extends throughout the length of the elongated body down to a second position on or proximate to the second end; as best seen in FIGS.1-10.

It is noted that Michelson did not teach of an implant that is comprised of cortical, cortical-cancellous, or cancellous bone; as claimed by applicant. However, Boyle et al evidences the use of an implant that is comprised of a cortical, cortical-cancellous, or cancellous bone so that the implant is remodel within the body after insertion and new bone will replace some or all the implant.

Therefore, given the teaching of Boyle et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the material of the implant of Michelson with the cortical bone material of Boyle et al so that the implant is remodel within the body after insertion and new bone will replace some or all of the implant.

With respect to claims 2-4, 9,17-19, the above combination of references discloses all the limitations, as set forth in Michelson columns 7-11, lines 1-67 and as best seen in FIGS: 1-38; and as set forth in Boyle et al., columns 4,5, lines 1-67, and as best seen in FIGS.1-21.

With respect to claim 23, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Claims 15,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rainey et al. (6,111,164) in view of Michelson (6,210,412).

With respect to claims 15,16, Rainey et al. disclose a method of producing a biomedical implant (10) that comprises an elongated body (12) having first and second

ends (FIG.1) wherein the first end comprises two or more oblique sides (18), the method comprising obtaining a bone having a ridge naturally formed thereon and excising bone block sections from the bone at an angle substantially perpendicular to the ridge; as best seen in FIGS. 2A-2C; and as set forth in column 2, lines 57-67 and column 3, lines 1-15.

It is noted that Rainey did not teach of an implant wherein the elongated body comprises a continuously tapered and threaded surface from about 5mm to about 25 mm in length; wherein the continuously tapered and threaded surface begins at a first position on or proximate to the first end and extends throughout the length of the elongated body down to a second position on or proximate to the second end; as claimed by applicant. However, in a similar art, Michelson evidences the use of an implant having such characteristics to increase implant stability and for the purpose of advancing the implant into the fusion site.

Therefore, given the teaching of Michelson, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the continuous tapered and threaded surface of Michelson in the device of Rainey et al to increase implant stability and for the purpose of advancing the implant into the fusion site.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (6,210,412) in view of Boyle et al. (6,277,149) in view of Rainey et al. (6,111,164).

With respect to claims 5,6,8, it is noted that the above combination of references did not teach of an implant defining a wedge shape and having pinch cuts out in the first end formed thereon; as claimed by applicant. However, in a similar art, Rainey et al. evidence the use of a dowel with pinch cut outs in the first end, defining a wedge edge to facilitate the positioning of the dowel into a bone opening for grafting.

Therefore, given the teaching of Rainey et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the wedge shape of Rainey et al in the device of Michelson/Boyle et al., to facilitate the positioning of the dowel into a bone opening for grafting.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (6,210,412) in view of Boyle et al. (6,277,149) in view of Branch et al (6,174,311).

With respect to claim 10, it is noted that the above combination of references did note teach of an implant having a peg portion in the first end to engage a securing device, as claimed by applicant. However, in a similar art, Branch et al, column 10, lines 48-65, evidence the use of peg portion for securely engaging a tool holder.

Therefore, given the teaching of Branch et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the peg portion of Branch et al in the device of Michelson/Boyle et al for securely engaging a tool holder.

Claims 11-14, 20-22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (6,210,412) in view of Boyle et al. (6,277,149) in view of Paul et al (6,258,125).

With respect to claims 11-14, 20-22,24, it is noted that the above combination of references teach all the limitations, except for an implant comprising two separate sections, as claimed by applicant. However, in a similar art, Paul et al, as best seen in FIGS 7,9,11, and column 4, lines 40-57, evidence the use of an implant having two separate sections to allow smaller sections of allergenic bone to be used for the fabrication of an implant.

Therefore, given the teaching of Paul et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Paul et al to fabricate the device of Michelson/Boyle et al to allow smaller sections of allergenic bone to be used for the fabrication of the implant.

Response to Amendment

Applicant's arguments with respect to claims 1-6,8-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,652,584	11-2003	Michelson
6,102,948	08-2000	Brosnahan, III
6,527,805	03-2003	Studer et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
December 30, 2003

PEDRO PHILOGENE
PRIMARY EXAMINER